



THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

Initiating Insulin as Part of the Treating To Target in Type 2 Diabetes (4-T) Trial An interview study of patients' and health professionals' experiences

Citation for published version:

Jenkins, N, Hallowell, N, Farmer, AJ, Holman, RR & Lawton, J 2010, 'Initiating Insulin as Part of the Treating To Target in Type 2 Diabetes (4-T) Trial An interview study of patients' and health professionals' experiences', *Diabetes Care*, vol. 33, no. 10, pp. 2178-2180. <https://doi.org/10.2337/dc10-0494>

Digital Object Identifier (DOI):

[10.2337/dc10-0494](https://doi.org/10.2337/dc10-0494)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

Diabetes Care

Publisher Rights Statement:

© Jenkins, N., Hallowell, N., Farmer, A. J., Holman, R. R., & Lawton, J. (2010). Initiating Insulin as Part of the Treating To Target in Type 2 Diabetes (4-T) Trial An interview study of patients' and health professionals' experiences. *Diabetes Care*, 33(10), 2178-2180doi: 10.2337/dc10-0494

General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact openaccess@ed.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.



Jenkins, N, Hallowell, N, Farmer, AJ, Holman, RR & Lawton, J 2010, 'Initiating Insulin as Part of the Treating To Target in Type 2 Diabetes (4-T) Trial An interview study of patients' and health professionals' experiences' *Diabetes Care*, vol 33, no. 10, pp. 2178-2180.

Title: Initiating insulin as part of the Treating to Target in Type 2 Diabetes (4-T) trial: A interview study of patients' and health professionals' experiences

Running title: Initiating insulin as part of 4-T

Authors

1) Dr. Nicholas Jenkins, Ph.D.

Centre for Population Health Sciences, University of Edinburgh

2) Dr. Nina Hallowell, D.Phil.

Institute of Health and Society, Newcastle University

3) Professor Andrew J Farmer, M.A., D.M., B.M., B.Ch., F.R.C.G.P.

Department of Primary Health Care, University of Oxford

4) Professor Rury R Holman, M.B., Ch.B., F.R.C.P

Diabetes Trials Unit, Oxford Centre for Diabetes, Endocrinology, and Metabolism, University of Oxford

5) Dr. Julia Lawton, Ph.D.

Centre for Population Health Sciences, University of Edinburgh

Corresponding author:

Dr. Nicholas Jenkins, Ph.D.; Centre for Population Health Sciences; University of Edinburgh; Medical School; Teviot Place; Edinburgh; EH8 9AG.

Tel: (+44)131 650 6197; Fax: (+44)131 650 6909. Email:

n.e.jenkins@ed.ac.uk.

Word count: Abstract = 137; Main Text = 996

Number of tables & figures: 1 Table

ABSTRACT

Objective: To explore patients' and health professionals' experiences of initiating insulin as part of the Treating to Target in Type 2 Diabetes (4-T) randomized controlled trial.

Research Design & Methods: Interviews were conducted with 45 trial participants and 21 health professionals and analyzed thematically.

Results: Patients were generally 'psychologically insulin receptive' when approached to participate in 4-T. Receptiveness arose largely from personal experiences of observing prior treatments intensify and blood glucose control deteriorate over time, which led patients to engage with and accept the idea that their diabetes was progressive. Health professionals also fostered receptiveness by drawing on their clinical experience to manage patients' anxieties about initiating insulin.

Conclusions: Previous studies may have over emphasized the problem of psychological insulin resistance, and overlooked factors and treatment experiences which may promote insulin receptiveness amongst type 2 patients.

According to the literature, psychological insulin resistance, resulting in delays in treatment initiation, can arise from patients' feelings of personal failure to self-manage their diabetes effectively and their anxieties about injecting, and from health professionals' clinical inertia and a lack of knowledge and experience of insulin therapy [1,2,3,4,5,6]. There is, however, limited qualitative research drawing upon patients' and health professionals' experiences of initiating insulin therapy. We report findings from a qualitative study involving patients and health professionals who, through their participation in the Treating to Target in Type 2 Diabetes (4-T) trial, initiated insulin using randomized analogue insulin regimens (basal, prandial and biphasic) [7,8].

RESEARCH DESIGN AND METHODS

Eleven of the 58 4-T centres were included in this study, selected to reflect diversity in centre size and geographical location. Patients and health professionals were recruited using an opt-in procedure. Patients were purposively selected so that the sample comprised equal numbers from across the trial's three treatment arms; was broadly representative of the wider trial population in terms of age, gender and glycemic control (Table 1); and included trial participants with high and low final HbA_{1c} results (range: 5.3 – 9.9%). At least one health professional from each centre was interviewed (9 physicians and 12 nurses).

The interviews - which explored (in-depth) participants' understandings and experiences of insulin initiation - were informed by topic guides and allowed

participants to raise issues which they perceived as salient. Interviews were conducted between October 2008 and July 2009, lasted between 40 minutes and 2 hours, were digitally recorded and fully transcribed. Data collection and analysis ran concurrently, with themes and hypotheses identified in early interviews informing questions in later interviews, in line with a grounded theory approach [9]. Data were coded using methods of constant comparison [9]. A qualitative data-indexing package (QSR Nvivo 2) facilitated data coding and retrieval.

RESULTS

Key finding

We had anticipated that negative beliefs about insulin, and resistance to start insulin therapy, would feature widely in patients' accounts. However, the vast majority were what we term 'psychologically insulin receptive' when approached to participate in 4-T. Key factors which fostered receptiveness are explored below.

Engaging with disease progression

For the majority of patients, the first time that they had been recommended insulin had been immediately prior to trial enrolment. Patients frequently claimed to have been upset, disappointed or shocked when advised that insulin was now needed. However, accounts of having personally failed to self-manage their diabetes – or resistance to initiating insulin - were extremely rare. Most described accepting that they required insulin because they

realized their diabetes had progressed. This realization arose from observing their oral glucose lowering medications (OGLMs) increase over time, often to maximum doses, and their glucose control deteriorate despite following their treatment regimens. Experiences of undertaking self-monitoring of blood glucose (SMBG) or comparing successive HbA_{1c} results facilitated patients' engagement with their disease progression. Armed with these experiences, some reported actually approaching their physician and requesting insulin:

"The doctor said anything under ten [mmol/l] was acceptable ... I started testing my blood sugar levels and that was really when I began to realize that tablets weren't helping me. So I went to the doctor and said, 'I want to go on insulin.'" (Pt20)

Managing anxieties about insulin therapy

Although psychologically receptive towards initiating insulin therapy, most patients described being anxious about the prospect of injecting. In most cases, these anxieties appeared to have been managed effectively by health professionals, who were usually highly experienced in initiating insulin. Patients frequently reported being pleasantly surprised upon discovering that they would be using insulin pens. These were seen as being more discrete, less painful to use, and easier to transport than the syringes they had anticipated using. Nurses described how encouraging engagement with SMBG results, prescribing low starting doses of insulin and supervising initial injections were some of their tried-and-tested techniques for easing patients' transition onto insulin. The structured programme of face-to-face and

telephone support delivered as part of 4-T provided health professionals with opportunities to employ these practices, in order to coax more anxious trial participants through the initiation period:

“I had one patient on the 4-T study who was not going to go on insulin because he was terrified of needles, and then I brought him in here and I said ‘Well, let me show you’, you know, and I got him to do an injection and he said ‘I didn’t feel anything’ and then he came into the study.” (HCP 1)

CONCLUSIONS

Previous studies have placed strong emphasis on the need to overcome patients’ psychological insulin resistance, yet they have also shown that the majority of their study participants were, in fact, willing to initiate insulin. For example, in one key paper focusing on psychological resistance to insulin, 71.7 % of non-insulin treated type 2 patients were, to varying degrees, willing to initiate insulin therapy, with almost a quarter being ‘very willing’ [2]. Also, 73% of patients randomized to the insulin arm of the UKPDS accepted treatment [10]. In line with these findings, our study suggests that receptiveness, rather than resistance, may be a more common experience amongst patients with type 2 diabetes. It is possible, therefore, that previous research has over-emphasised the difficulties associated with resistance, to the detriment of exploring factors which can promote receptiveness.

Encouraging SMBG at the point where insulin is being recommended, and educating patients about acceptable ranges for their readings, may help

promote psychological insulin receptiveness, as might discussion of HbA_{1c} results in diabetes review visits. Providing patients with insulin pens and a structured programme of support during initiation may also help patients to overcome their anxieties about insulin.

Limitations of the study

The study was limited to the United Kingdom. The vast majority of interviewees were White-British. By virtue of having agreed to participate in 4-T, patients may have held more positive beliefs about insulin than those in non-trial settings.

N.J., J.L. and NH researched data and wrote manuscript. A.F. and R.R. contributed to discussion and reviewed/edited manuscript.

ACKNOWLEDGEMENTS

The qualitative interview study was funded by Diabetes UK (award ref: BDA 08/0003702) and funding for the preliminary work was provided by Novo Nordisk. Some of these data were presented at the 4-T Final Investigator Meeting in November 2009. We are grateful to all the 4-T patients and practitioners who took part in this study and to Julie Darbyshire, Rachel Roberts (University of Oxford) and Lisa Horsburgh (University of Edinburgh) for their help and assistance.

DISCLOSURE

Rury R. Holman reports receiving grant support from Asahi Kasei Pharma, Bayer Healthcare, Bayer Schering Pharma, Bristol-Myers Squibb, GlaxoSmithKline, Merck, Merck Serono, Novartis, Novo Nordisk, Pfizer, and Sanofi-Aventis, consulting fees from Amylin, Eli Lilly, GlaxoSmithKline, Merck, and Novartis, and lecture fees from Astella, Bayer, GlaxoSmithKline, King Pharmaceuticals, Eli Lilly, Merck, Merck Serono, Novo Nordisk, Takeda and Sanofi-Aventis. No other potential conflict of interest relevant to this article was reported.

REFERENCES

- 1) Brod M, Kongsø JH, Lessard S, Christensen TL. Psychological insulin resistance: patient beliefs and implications for diabetes management. *Qual Life Res* 2009; 18(1):23-32
- 2) Polonsky WH, Fischer L, Guzman S, Villa-Caballero L, Edelman SV. Psychological insulin resistance in patients with type 2 diabetes: the scope of the problem. *Diabetes Care* 2005; 28(10): 2543-2545
- 3) Korytkowski M. When oral agents fail: practical barriers to starting insulin. *Int J Obes Relat Metab Disord*. 2002; 26 Suppl 3: S18-S24
- 4) Peyrot M, Rubin RR, Lauritzen T, Skovlund SE, Snoek FJ, Matthews DR, Landgraf R, Kleinebreil L. Resistance to insulin therapy among patients and providers: Results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care* 2005; 28(11): 2673-2679
- 5) Cefalu WT, Mathieu C, Davidson J, Freemantle N, Gough S, Canovatchel W. Patients' perceptions of subcutaneous insulin in the OPTIMIZE study: A multicenter follow-up study. *Diabetes Technol & Ther* 2008; 10(1): 25-38

- 6) Hunt LM, Valenzuela MA, Pugh JA. NIDDM patients' fears and hopes about insulin therapy: The basis of patient reluctance. *Diabetes Care* 1997; 20(3): 292-298
- 7) Holman RR, Thorne KI, Farmer AJ, Davies MJ, Keenan JF, Paul S, Levy JC. Addition of biphasic, prandial, or basal insulin to oral therapy in type 2 diabetes. *N Engl J Med* 2007; 357: 1716-1730
- 8) Holman RR, Farmer AJ, Davies MJ, Levy JC, Darbyshire JL, Keenan JF, Paul SK. Three-year efficacy of complex insulin regimens in type 2 diabetes. *N Engl J Med* 2009; 361: 1736-1747
- 9) Strauss AL, Corbin JM. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. Newbury Park, CA, Sage, 1990
- 10) UK Prospective Diabetes Study Group. UKPDS 13. Relative efficacy of randomly allocated diet, sulphonylurea, insulin, or metformin in patients with newly diagnosed non-insulin dependent diabetes followed for three years. *BMJ* 1995 (6972); 310: 83-88

Table 1 Patient characteristics

Patients	4-T (n=708)	Qualitative sample (n=45)
Age		
Mean age (\pm SD)	61.7 (\pm 9.8)*	64.7 (\pm 8.5) †
Sex		
Male	454	29
Female	254	16
Randomisation		
Biphasic	235	15
Prandial	239	15
Basal	234	15
Glycated hemoglobin at Yr 3		
Median HbA _{1c}	6.9%	6.9%
Number (%) of patients with HbA _{1c} \leq 7%	425 (60)	26 (58)
Number (%) of patients with HbA _{1c} \leq 6.5%	283 (40)	19 (42)
Notes		
* Age at trial initiation		
† Age at interview		